510(k) SUMMARY

K040906

NAME & ADDRESS: DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, PA 17404
Telefax (717) 849-4343

JUN 1 6 2004

CONTACT: P. Jeffery Lehn

DATE PREPARED: April 2, 2004

TRADE OR PROPRIETARY NAME: CALIBRA™ CEMENT

CLASSIFICATION NAME: Dental cement (872.3275)

PREDICATE DEVICES: Enforce™ with Fluoride Cement K940459

DEVICE DESCRIPTION: CALIBRA™ CEMENT is a visible light cured (VLC), dual-cured, or self-cured high strength cement that, with compatible dentin/enamel adhesive systems, adhesively bond and lute indirect restorations to tooth structure.

CALIBRA™ CEMENT consists of VLC base paste and catalyst paste. The base paste is mixed with the catalyst paste to form a dual-cured cement. This mixed version of the cement will self-cure or can be light-cured, or both.

CALIBRA™ CEMENT also includes a set of try-in pastes. These try-in pastes are highly water-soluble and easily rinsed away, and are used to mimic the shade of the cured cement prior to final cementation in order to ensure a good match to the adjacent dentition.

INTENDED USE: CALIBRA™ CEMENT is indicated for the adhesive cementation of: 1) ceramic, porcelain, or composite inlays/onlays, veneers, or crowns; 2) all metal crowns, bridges, inlays/onlays including precious, semi-precious, and non-precious metals; 3) PFM (porcelain fused to metal) crowns and bridges; 4) prefabricated and cast posts; and 5) resin-bonded retainer bridges (Maryland bridges).

TECHNOLOGICAL CHARACTERISTICS: All of the components found in CALIBRA™ CEMENT have been used in legally marketed devices.

Because of the nearly equivalent material composition of CALIBRA™ CEMENT to the predicate device, no additional toxicity testing was necessary.

We believe that the prior use of the components of CALIBRA™ CEMENT in legally marketed devices and the performance data provided support the safety and effectiveness of CALIBRA™ CEMENT for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 6 2004

Mr. P. Jeffery Lehn
Director of Corporate Compliance and Regulatory Affairs
Dentsply International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17404

Re: K040906
Trade/Device Name: CALIBRA™ CEMENT
Regulation Number: 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: April 5, 2004
Received: April 7, 2004

Dear Mr. Lehn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

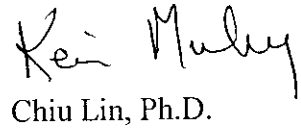
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address

Sincerely yours,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K040906

Device Name: CALIBRA™ CEMENT

Indications for Use:

Adhesive cementation of:

1) ceramic, porcelain, or composite inlays/onlays, veneers, or crowns;
2) all metal crowns, bridges, inlays/onlays including precious, semi-precious, and non-precious metals;
3) PFM (porcelain fused to metal) crowns and bridges;
4) prefabricated and cast posts; and
5) resin-bonded retainer bridges (Maryland bridges)

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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